

d.) Remarks.

Applicant has amended the specification to indicate that this is a continuation application, and also claims 1, 21, 46 and 65, all as was requested by the Examiner. No new matter or new issues are presented with these amendments. Accordingly, claim 1-29, 46-75 are currently pending.

Remarks Regarding Oath/Declaration

The Declaration submitted with the application was considered defective by the Examiner (at the Interview of June 28, 2005) because it does not identify the citizenship of each inventor. As requested by the Examiner, a substitute Declaration, clearly identifying the citizenships of the inventors, is enclosed.

Remarks Regarding Double Patenting

Claims 1-9, 11-20, 22-29, 46-53, 55-59, 65, 70, 73, 74 and 75 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting, as allegedly obvious over claims 1-20, 22, 24, 26-29, 46-53 and 55-59 of co-pending Application No. 09/816,152. Both applications are 100% owned by applicant. Solely to expedite prosecution, enclosed is an appropriate Terminal Disclaimer and, thus, this provisional rejection is moot.

Remarks Regarding 35 U.S.C. § 132(a)

The Amendment filed 4/20/05 and 5/12/05 is objected to, under 35 U.S.C. § 132(a), as allegedly introducing new matter into the disclosure. Applicant respectfully traverses this objection.

In the Office Action, it is alleged that the amendments to claims 1, 21, 46 and 65 entered by applicant's prior Amendment are not supported in the specification. Specifically, the Examiner objects to the phrases:

- (i) "... *medical information contained within said medical record is verified as to accuracy of transcription and certified for accuracy of transcription;*" claim 1;
- (ii) "... *wherein the medical information in said at least one medical record is certified as to accuracy of transcription;*" claim 21;
- (iii) "... *certifying that the portion transmitted is accurate as to transcription;*" claim 46; and
- (iv) "... *medical records is verified as to accuracy of transcription and certified as to accuracy of transcription and thereby posses the characteristic of non-repudiation;*" claim 65.

Applicant respectfully asserts that all the amendments are supported in the specification both literally and as understood by one skilled in the art. For example, the broad concepts of "certification" and "verification" are all thoroughly discussed in the specification, for example, at pages 15-17 and 20-23. In one instance, it states in the specification that:

"Certification may simply state that the record is correct in all material respects or that the record is internally consistent. Errors in medical records may be corrected (with appropriate annotation) or simply noted...Suggestions in the form of supplemental...computerized evaluations or other helpful comments may be included with comprehensive certification as to possible diagnosis, possible treatment or health options, and the like. Thus, a part of each level of certification may be verification that the information is exactly as it appears in the paper or other tangible or even electronic file of the original source, or possibly better"
(specification, page 16, lines 12-19).

Additional support for the phrases "non-repudiation" and "accuracy" are also found throughout the specification and, in particular, at page 17, lines 14-17, which states that "*medical records that are verified as accurate attain the aspect of non-repudiation (i.e. that the accuracy and correctness of the information is as good or better than exists at the source sites from which the records were obtained)*".

Applicant also respectfully notes that both literal and contextual support for the phrases “transcription” and “accuracy of transmission” are found in various parts of the specification, such as, at page 18, line 10 (“*translation and transcription means*”), and also at page 22, line 17 (“*transmitted accurately*”). Additional support can also be found in the specification at page 16, lines 17-19 (“*that the information is exactly as it appears in the paper or other tangible or even electronic file*”). Each of these instances provides more than sufficient support for the phrases “transcription” and “accuracy of transcription.”

In view of applicant’s remarks above, this objection is believed to be overcome.

Please note that claims 1, 46 and 65 have been amended to delete the phrase “of transcription,” but that this phrase remains in claim 21.

Remarks Regarding 35 U.S.C. § 112, First Paragraph

Claims 1, 21, 46 and 65 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite for the same reason as set forth in the above objection to alleged new matter. Applicant respectfully traverses this rejection and incorporates all remarks made above regarding the objection under 35 U.S.C. § 132(a). In view of applicant’s above remarks, this rejection is believed to be overcome.

Remarks Regarding 35 U.S.C. § 112, Second Paragraph

Claims 1-19 and 60-75 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

It is alleged that the phrases “can be” and “may be” in claims 1 and 65 render the claims indefinite. It is respectfully noted that these phrases were discussed at the Interview of June 28, 2005. It was understood from that Interview that these phrases were acceptable. Although applicant respectfully disagrees with this rejection, solely to expedite prosecution, claims 1 and 65 have been amended to substitute the phrase “capable of being,” where appropriate. Thus, this rejection is moot. However, if a

different phraseology is preferred by the Examiner, to expedite prosecution, applicant respectfully requests that the Examiner telephone the undersigned.

Remarks Regarding 35 U.S.C. § 103(a)

- A. Claims 1-11, 18-26, 29, 46, 47 and 51-75 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden (U.S. Patent Application No. 2002/0026332 A1), and further in view of Shepard (U.S. Patent No. 6,026,363).
- B. Claim 12 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Baker (PCASSO).
- C. Claims 13-15, 27, 28 and 48-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Malik (U.S. Application No. 2001/0037219 A1).
- D. Claims 16 and 17 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Snowden in view of Shepard, and further in view of Shear (U.S. Patent No. 4,827,508).

Not One of the Cited Combinations Suggests Applicant's Claimed Invention

Applicant respectfully traverses these rejections and incorporates all remarks set forth in all of applicant's prior Responses. Applicant also respectfully traverses all of the Examiner's comments in the Office Action including all of the Examiner's conclusions with respect to the cited references and especially, as discussed more fully below, with respect to Snowden, Malik and Shepard. None of the references in the Office Action discloses or suggests, either alone or in combination, applicant's claimed invention.

In the Office Action, the Examiner states that the phrase "data integrity" implies the characteristic of non-repudiation. Applicant respectfully disagrees. Data integrity, as disclosed in Snowden (*see* Snowden, paragraph 121), does not imply a characteristic of non-repudiation as claimed by applicant (*see* specification, page 21, lines 20-28).

Applicant provides the following additional remarks with respect to Snowden, Malik and Shepard.

Snowden is not Prior Art

With respect to Snowden, applicant respectfully asserts that Snowden does not disclose or suggest, either alone or in combination with any one or more references of record, applicant's claimed invention. Nevertheless, to expedite prosecution, enclosed is a declaration, by the inventors in compliance with 37 C.F.R. § 1.131 (the "Rule 131 Declaration"), in which the inventors assert that their claimed invention, at least to the extent alleged by the Examiner to be disclosed in Snowden, was conceived and reduced to practice prior to the filing date of the provisional application which became Snowden, in other words, prior to December 6, 1999. In support of this Declaration, attached thereto is a review (the "Review"¹) setting forth aspects of the instant invention, that was prepared by the inventors prior to the filing of the Snowden provisional application.

To assist the Examiner in her evaluation of the Review, applicant provides the following remarks highlighting certain of the statements within the Review (line numbers were added by the undersigned).

First, applicant directs the examiner to page 3, lines 8-9 of the Review, which discusses the concept of the "*trusted agent*" for maintaining medical information "*via the web*" (see also, page 6, line 14: "*A man is recently diagnosed with prostate cancer. He has the results from his physical and laboratory tests. He goes to the 'trusted agent'*").

As further discussed at page 3, lines 9-14: "*The trusted agent would search a variety of objective and valid sources to obtain comprehensive state of the art individualized medical information, prognoses, and a comprehensive assessment of*

¹ The attached document, cited herein as the "Review," was previously disclosed, in confidence, to a select few people by the inventors. Applicant is disclosing that document here, but with all non-relevant information such as information about the individuals who received copies redacted. Although the redactions are not proprietary to applicant, applicant does not wish to place such personal information into the public record. If the Examiner would like to review the redacted portions, the undersigned will provide the Examiner a copy for reviewing at a personal interview. Because the Review is being made public here, it is also being provided, again in redacted form, on an Information Disclosure Statement being filed contemporaneously herewith.

treatment alternatives and likely outcomes. The structure of this information would enable individual consumers to interpret the findings and then interact with clinicians and health care delivery systems as informed consumers and prudent purchasers of specific services.”

Additional discussion at page 4, lines 35-39, recites that one would use: “*the power of the Internet to develop a new model for healthcare information dissemination and interpretation*” and “*the individual patient would be the main repository [of] their medical information.*” It is clear that individuals would access their medical information and “*‘carry’ the results with them to all medical encounters regardless of location*” (page 4, lines 40-41).

At page 5, lines 2-5, the Review also states that “*the medical care system would need have ‘read-only’ information systems. They would be capable of receiving individual patient data and recommendations and then updating it with current data at the end of the encounter and then return it to the patient.*”

Further still, the Review states that; “*The simple but powerful rationale behind this effort is that all healthcare transactions are centered on the patients or patient data.*” (page 5, lines 6-7). Also at page 5, “*The demands of privacy (and the draft HIPPA regulation) will increasingly stress data transfer security and encourage ‘ownership’ and dissemination of this detailed data to individual.*” (lines 33-35).

Also at page 5, the Review states that: “*The patient, members of their family, or trusted advocates are also the most interested in insuring that their medical information be accurate and the advice given appropriate.*” (lines 8-10). “*Because most services would still be provided through the practitioner, the information and data provided by the trusted agent would have to be respected and acknowledged by the clinician.*” (page 5, lines 19-21).

The above-noted quotes from the Review are provided for the convenience of the Examiner only. Other sections of the Review are believed to disclose the same and other aspects alleged to be found in Snowden as noted by the Examiner in the Office Action.

Accordingly, applicant respectfully requests that the Examiner consider the entirety of the Review.

In view of applicant's Rule 131 Declaration, Snowden cannot be considered prior art to applicant's claimed invention. Because all prior art rejections in the Office Action are based on Snowden, all such rejections are now moot and applicant respectfully requests that they be withdrawn.

Malik is not Prior Art

Applicant respectfully directs the examiner's attention to page 5, lines 33-35 of the Review, which discloses the feature of privacy and security, and the need to comply with HIPPA. These are the aspects alleged by the Examiner in the Office Action to be disclosed by Malik.

Malik claims priority to Provisional Application No. 60/200,091, which was filed on April 27, 2000. This date is almost six months after applicant's Rule 131 date, and thus, Malik can no longer be considered prior art to applicant's claimed invention.

Shepard Teaches Away from Applicant's Invention

With respect to Shepard, applicant respectfully asserts that Shepard is not combinable with Snowden and would not lead one skilled in the art toward applicant's invention. In contrast to applicant's claimed invention, which is directed to patient-based records, Shepard is directed to the conventional hospital-based or physician-office system, or, in other words, to a source-centered record system, which leads one skilled in the art exactly in the wrong direction. As stated in applicant's specification: "*Integration of medical information is patient-centered, not source- or physician-centered...*" (emphasis added) (specification, page 7, lines 16-17). As is well-established, a "teaching away," as we have here, is the strongest indication of the non-obviousness of applicant's claimed invention.

As is clear from a full reading of Shepard, the Shepard medical record management system is directed to a hospital-based system wherein medical records are

physician- or clinician-centered. As discussed in Shepard, an advantage of their invention is that medical records are to be recorded by a “*medical history documentation system [that] uses a second person who functions as the recorder and is present during the physical examination and/or treatment by the first person who is the health care professional*” (emphasis added) (see Shepard, column 6, lines 52-57). Shepard even highlights this fact by stating that the recorder of the medical information prepares a Report Form for review by the examining physician before that physician verifies and signs-off on the report (Shepard, column 11, lines 58-67). Only then is the report considered a “Final Report Form” and suitable for placing in the patient’s medical record. Thus, although such records are alleged to be verified, they would be verified as correct only by the health care professional who conducted the examination. This is not a patient-based record system as described in the instant application, but a very conventional hospital-based record system for creating original medical records.

Further, there is no vetting or certification according to applicant’s claimed invention. The parts of Sheppard alleged in the Office Action to disclose or suggest vetting and/or certification are column 1, lines 29-37; column 4, line 60 to column 5, line 11; column 5, lines 58-62; column 6, lines 8-13; column 8, lines 44-48; column 12, lines 8-12; column 13, line 54 to column 14, line 9; and column 14, lines 61-65.. Applicant has reviewed each of these sections and none discloses or suggests vetting or certification according to applicant’s claimed invention. All of these instances noted in Shepard refer to verification of the patient’s record by the physician or health care worker who is tasked with creating the record in the first place. The main idea behind Shepard is to delegate the task of actually writing the medical record to another person who is not administering the care. That person is, for example, to be present in the room when the patient is being examined by the physician (Shepard, column 6, lines 52-57). However, once drafted by the recorder, the draft record is provided to the care-giver, most typically the physician, for final review before it becomes a part of the patient’s medical record. In other words, although Shepard may describe a system to create “original” medical records, Shepard

neither discloses nor suggests vetting or certification according to applicant's claimed invention. This highlights another aspect of applicant's claimed invention, which is recited in claim 20, and clearly distinguishes the instant claims from Shepard.

With reference to instant claim 20, and in contrast to the Examiner's allegation, the information contained within Shepard's medical records cannot be better than exists at the source from which the record was obtained. This is at least because the hospital, physician or health care worker "is" the source of the record. In other words, the Shepard system envisions creating original medical records. Therefore, Shepard can not logically be a system of creating medical record that are "better" than exist at the source from which the records were originally obtained (*i.e.* better than the original record).

For at least these reasons, Shepard clearly teaches away from applicant's claimed invention. Further, the proposed combination with Snowden is not logical, nor is a combination of Shepard with any reference of record. Accordingly, applicant respectfully requests that all rejections based on Shepard be withdrawn.

In sum, because all obviousness rejections of the Office Action are based on Snowden, Shepard and/or Malik, all such rejections are both moot and overcome.

Conclusion

The application including pending claims 1-29 and 46-75, are believed to be in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested.

If the Examiner believes that another interview, either in person or by telephone, would advance the prosecution of this application, such an interview would be welcomed, and the Examiner is encouraged to contact the undersigned.

No fees are believed to be due with the filing of this Amendment. However, if any fees are later determined to be due, including any fees for an extension of time, applicant respectfully requests that extension and that all such fees be charged to **Deposit Account No. 50-1682, referencing Attorney Docket No. 144009.00200.**

Respectfully submitted
POWELL GOLDSTEIN LLP,

Date: August 26, 2005

By: _____

James Remenick
Attorney for Applicant
Registration No. 36,902

Enclosed: Terminal Disclaimer
Substitute Declaration
Rule 131 Declaration
Information Disclosure Statement

Customer No. 51362
Powell Goldstein LLP
901 New York Ave., N.W.
Suite 300
Washington, DC 20001-4413
Telephone: (202) 347-0066
Facsimile: (202) 624-7222